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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,897	06/07/2005	Ana Isabel Sanz Molinero	BJS-4982-5	8027
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NIXON & VANDERHYE, PC			BAUM, STUART F	
901 NORTH GLEBE ROAD, 11TH FLOOR				
ARLINGTON, VA 22203			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<i>Office Action Summary</i>	Application No.	Applicant(s)
	10/537,897	SANZ MOLINERO, ANA ISABEL
	Examiner STUART F. BAUM	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 March 2008 and 18 November 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,10-17,19-23,29-34 and 43-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,10-17,19-23,29-34 and 43-56 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 07 June 2005 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/7/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. The amendments filed 3/31/2008 and 11/18/2008 have been entered.
2. Claims 1-4, 10-17, 19-23, 29-34, 43-56 are pending.
Claims 5-9, 18, 24-28 and 35-42 have been canceled.
3. Claims 43-52 have been newly added in the amendment filed 3/31/2008 and are drawn to the elected invention.
4. Newly submitted claims 53-56 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 53-56 are drawn to many sequences including SEQ ID NO:2.

Applicant is reminded that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another, as are different proteins structurally distinct chemical compounds and unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq (see MPEP 803.04 and 2434). This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Applicants provisionally elected SEQ ID NO:1 encoding SEQ ID NO:2 in the response filed 8/30/2007.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, SEQ ID NO:13, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, 35, 37, 39, 46, and 50 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5. Claims 1-4, 10-17, 19-23, 29-34, 43-56, including SEQ ID NO:1, 2, 5, 7, 8, and 9 are examined in the present office action.

The restriction is made FINAL.

Claim Objection

6. Claim 2 is objected to for omitting the “%” sign after the recitation “80”.

Claim 2, line 20 is objected to for reciting “increasing” instead of --increased--.

Claim 30, line 1 is objected to for reciting “a method” instead of --the method--.

Claim 47, line 3 is objected to for reciting “sequences” instead of --sequence--.

Claim 54, line 8 is objected to for reciting “increasing” instead of --increased--.

Claim 55, line 9 is objected to for reciting “prolonging” instead of --prolonged--.

Claims 55 and 56 are objected to for omitting the recitation --grown-- between the words “plant” and “under”.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4, 10-17, 19-23, 29-34 and 43-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

In claim 1, it is unclear whether or not the “(SEQ ID NO:51)” is intended as a claim limitations or to which sequence “(SEQ ID NO:51)” belongs. All subsequent recitations in which a SEQ ID NO is set in parentheses are also rejected.

Claim 1 is indefinite for reciting “80% sequence identity to SEQ ID NO:5 or 7 or 8 or 9”. SEQ ID NO:5 consists of 6 amino acids. Given the length of the sequence, the mathematical possibilities for percent identity are for example, 83% and 66%. Given SEQ ID NO:7 consists of 7 amino acids, the closes mathematical possibility to 80% is 86%. Given SEQ ID NO:8 consists of 7 amino acids, the closes mathematical possibility to 80% is 86%. Given SEQ ID NO:9 consists of 12 amino acids, the closes mathematical possibility to 80% is 83%. All subsequent recitations of “80% sequence identity to SEQ ID NO:5 or 7 or 8 or 9” are also rejected.

Claims 54-55 recites the limitation "modified". There is insufficient antecedent basis for this limitation in the claim.

Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

§ 2172.01. The omitted steps are: selecting for a plant having increased leaf surface area or prolonged vegetative growth.

Written Description

8. Claims 1-4, 10-17, 19-23 and 29-34 remain rejected and new claims 43-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/30/2007. Applicant's arguments filed 11/18/2008 have been fully considered but they are not persuasive.

Applicants contend essential regions set forth in SEQ ID NO:5, 7, 8 and 9 are identified on page 14 and that one of ordinary skill in the art will appreciate from the present specification that it is not necessary to include all the regions present in order to perform the methods of the claimed invention (page 18 of Remarks, 3rd paragraph).

The Office contends that Applicants do not disclose regions of SEQ ID NO:2 that are essential and sufficient for producing the claimed phenotypes when incorporated in the claimed methods and plants. Applicants have not disclosed any sequence encoding a polypeptide comprising an amino acid sequence that exhibits 80% identity to SEQ ID NO:5, 7, 8 and 9 and produces the claimed phenotypes when expression of said sequence is increased.

Applicants contend page 6, lines 14-23 of the application describes variants of 2xC2H2 nucleic acids and their encoded protein that are useful in the claimed invention (page 18 of Remarks, 4th paragraph). Applicants contend pages 6-16 describes variants, homologues and orthologues whose sequences are given in SEQ ID NO:12 to 25. Applicants contend SEQ ID NO:26 to 35 disclose homologues from the same species (paragraph bridging pages 18 to 19 of Remarks). Applicants contend examples of alternative cDNAs encoding SEQ ID NO:2 are given on page 15.

The Office contends that the word “homologous” when used in the context of nucleic acid sequences encoding proteins has an evolutionary component. For example, genes that are similar in different organisms owing to their having inherited them from a common ancestor (see homologous definition-Ayala and Kiger, *In Modern Genetics*, second edition, The Benjamin/Cummings Publishing Company, Menlo Park, California, 1984). Therefore it is unclear what SEQ ID NO:26 to 35 represent, given that they all originate from the same species. In addition, the Office contends that the information on page 6 is prophetic. Applicants do not provide examples of :

- (i) Functional portions of a 2xC2H2 zinc finger nucleic acid/gene;
- (ii) Sequences capable of hybridising with a 2xC2H2 zinc finger nucleic acid/gene;
- (iii) Alternative splice variants of a 2xC2H2 zinc finger nucleic acid/gene;
- (iv) Allelic variants of a 2xC2H2 zinc finger nucleic acid/gene;
- (v) Homologues, derivatives and active fragments of a 2xC2H2 zinc finger protein (page 6 of Remarks, lines 18-22);

that are used in the claimed method.

Applicants contend page 15 provides several cDNAs encoding the same protein as that of SEQ ID NO:2 (page 19 of Remarks, bottom paragraph).

The Office contends that the specification discloses that the listed cDNAs encode the same protein but have different 5' and 3' UTR that specify different expression patterns.

Applicants state “The applicants believe however that the specification provides a sufficient representative number of examples that when taken together with those provided on page 15 and on Table 9 of the application, and the sequence listing, the figures, and the guidance provided on how to find other candidate sequences provides a precise definition of the 2xC2H2 genus, such that one of ordinary skill in the art will appreciate that the applicants were in possession of the claimed invention at the time the application was filed” (page 20 of Remarks, top paragraph). Applicants describe structural features of SEQ ID NO:2 as set forth in SEQ ID NO:5, 7, 8 and 9 (page 20, 1st full paragraph). Applicants disclose that Annex 3 contains a sequence alignment of multiple sequences of 2XC2H2 proteins as found in the sequence listing wherein positional motifs as represented by SEQ ID NO:5, 7, 8 and 9 are indicated (page 20 of Remarks, bottom paragraph). Applicants disclose that Annex 4 provides an alignment of multiple 2XC2H2 proteins as described in the paragraph bridging pages 15-16 and motifs as represented by SEQ ID NO:5, 7, 8 and 9 are indicated (paragraph bridging pages 20-21 of Remarks). Applicants disclose Annex 6 contains SEQ ID NO:7, 8 and 9 and calculation (page 21 of Remarks, top paragraph).

The Office contends Applicants have not disclosed a nucleic acid encoding a polypeptide comprising a sequence having at least 80% identity to SEQ ID NO:5, 7, 8 and 9, as recited in the claims, that when the expression of said sequence is increased in a plant, the plant exhibits an increase in yield, increase in leaf surface area, or has a prolonged vegetative phase, or wherein the increased yield comprises an increased root yield or increased seed yield or increased above

ground biomass. In addition, Applicants have not disclosed any alternative splice variants , allelic variants, homologues, derivatives or active fragments or a sequence that exhibits 80% sequence identity to SEQ ID NO:2 that are operable in Applicants' invention. The Office contends the list of sequences on page 15 have not been shown to produce the same effect as SEQ ID NO:1. For example, Accession Number BAA21923 is a zinc finger protein but does not comprise SEQ ID NO:9 and it is only 166 amino acids, whereas Applicants' SEQ ID NO:2 is 225 amino acids. The Office acknowledges the alignment of sequences in Annex 3 and 4 and the percent identity of SEQ ID NO:7, 8 and 9 as they appear in different sequences. In regards to the sequences presented in Annex 3, 4 and 6, Applicants have not shown that the disclosed sequences produce the desired effect when their expression is increased in a plant. The Office contends Applicants have presented sequences that are in the 2XC2H2 gene family but they have not disclosed all the essential regions of a protein that are required to produce the desired result and Applicants have not disclosed a representative number of sequences from a representative number of plant species that encode a polypeptide that when transformed into a plant produces the desired result.

Scope of Enablement

9. Claims 1-4, 10-17, 19-23 and 29-34 remain rejected and new claims 43-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for increasing plant yield, method for increasing leaf surface area, method for prolonging vegetative growth phase and method for the production of a transgenic plant having increased yield comprising transforming a plant with a construct comprising a constitutive promoter

operably linked to SEQ ID NO:1 encoding SEQ ID NO:2, does not reasonably provide enablement for said methods comprising any sequence encoding a protein exhibiting less than 100% sequence identity to SEQ ID NO:2, or any method of modifying expression of a nucleic acid sequence encoding a polypeptide comprising a sequence having at least 80% sequence identity to SEQ ID NO:5, 7, 8 and 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/30/2007. Applicant's arguments filed 11/18/2008 have been fully considered but they are not persuasive.

Applicants contend Annex 1 contains data using two additional sequences that were transformed into either Arabidopsis or rice, SEQ ID NO:26 encoding SEQ ID NO:27 and SEQ ID NO:36 encoding SEQ ID NO:37, respectively (page 22 of Remarks, top paragraph). In both cases the transformed plants exhibited increased yield, increased leaf surface and prolonged vegetative growth. Applicants disclose the identity between SEQ ID NO:2 and SEQ ID NO:37 is 42% and between SEQ ID NO:2 and SEQ ID NO:37 is 31%. Applicants disclose that rice plants transformed with SEQ ID NO:28 also increased yield and the results are presented in Annex 5 (paragraph bridging pages 22-23 of Remarks).

The Office invites Applicants to submit a declaration under 37 CFR 1.132 containing the information submitted in Annex 1-6, for consideration by the Office (See MPEP 716.01 (c)). However, the Office notes that Applicants have not aligned SEQ ID NO:2, 27 and 37 by themselves.

Applicants contend sequences are disclosed on pages 13-16 of the specification that provide ample teaching of structural features common to members of the claimed genus that can be used in Applicants' method. These sequences provide guidance for one skilled in the art to identify other sequences that would be operable in Applicants' invention (page 23 of Remarks, 1st full paragraph to page 24, 1st full paragraph). Applicants contend that the information from Annex 1 demonstrates that the specification is enabling, i.e., one skilled in the art can use the information from Applicants' disclosure and isolate sequences from plants that would be operable in Applicants' invention (page 24 of Remarks bottom paragraph to page 25, top paragraph).

The Office contends Applicants have not taught the activity of all the proteins disclosed on pages 13-16. Applicants have only stated that they are "homologous" sequences, but it is not clear if each and every sequence has the same activity. For example, Applicants state "Other close homologues useful in the methods...from petunia:" (page 15, lines 32-34) and then presents a list of 18 sequences. On page 16, Applicants list another group of accession numbers representing sequences from Arabidopsis and rice that presumably are homologues but Applicants have not indicated what is the activity of each sequence. The prior art is also silent about their activity. Therefore, one of skill in the art would have to test each and every sequence which constitutes undue trial and error experimentation, given the reasons of record as stated in the previous office action.

Applicants contend transforming plants with heterologous nucleic acid sequences can produce predictable results and gives two examples, i.e., AtNHX1 and CBF1 (page 25 of Remarks, 2nd paragraph to the bottom of page 25). Applicants contend the present specification

discloses methods to search and identify the sequences encompassed by the claims and methods are known in the art (page 26 of Remarks, 2nd paragraph). In addition, Annex 1 discloses the results of using methods taught in the specification to isolate additional sequences that produce the claimed invention.

As stated above, Applicants are invited to submit the information from Annex 1-6 in a declaration under 37 CFR 1.132. Claim 1 as currently amended is directed toward a polypeptide comprising four motifs, i.e., a sequence having at least 80% identity to SEQ ID NO:5, 7, 8 and 9. The recitation of a polypeptide comprising four motifs, i.e., a sequence having at least 80% identity to SEQ ID NO:5, 7, 8 and 9 represents a partial structure. That is, the claimed polypeptides share 80% identity with SEQ ID NO:5, 7, 8 and 9 but no structure/function correlation has been presented. Applicants have not presented an assay for determining which motifs having 80% identity to SEQ ID NO:5, 7, 8 and 9 are functional and which are not. In addition, Applicants have not disclosed how one skilled in the art would determine which polypeptides having 80% identity to SEQ ID NO:5, 7, 8 and 9 also have the requisite structure to be operable in Applicants' invention. Applicants are claiming a genus of polypeptides based on four motifs comprising about 30 amino acids. Applicants are silent about the rest of the amino acids that are required for the claimed polypeptide. There is no teaching in the specification regarding which amino acids can be varied while retaining the required activity to produce a plant having increased yield, increased leaf area or prolonged vegetative growth. Consequently, there is no information about which amino acids can vary from SEQ ID NO:2 in the claimed genus of polypeptides and still retain the catalytic activity.

Briefly, for claims drawn to 80% identity to SEQ ID NO:2, Applicants have not taught which of the claimed sequences have the proper activity that when increased produce the desired result. Applicants have only disclosed the structure of SEQ ID NO:2.

Therefore, Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)).

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 30-34 remain rejected and new claim 52 is rejected under 35 U.S.C. 102(b) as being anticipated by Pineda et al (2001, WO 01/36598 A1). This rejection is maintained for the reasons of record set forth in the Official action mailed 11/30/2007. Applicant's arguments filed 11/18/2008 have been fully considered but they are not persuasive.

Applicants contend the cited document fails to teach or suggest, for example, selecting for plants having increased yield (page 27 of Remarks, 2nd full paragraph).

The Office contends it would be inherent for a plant having increased expression of SEQ ID NO:2 to exhibit the claimed phenotypes. “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v.*

Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed.Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In addition, see *In re Cruciferous Sprout Litigation*, 64 USPQ2d 1202, (Fed. Cir. 2002), which teaches that newly recognized constituents or properties of a prior art product are inherent properties which do not render claims to that product patentable.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 30 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 30 is drawn to a harvestable part, propagule or progeny which the Office interprets to read on seeds. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed harvestable part, propagule or progeny (seeds), it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S.

303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy , Coats, and Malik* 195 USPQ 344, (CCPA) 1977.

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638
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